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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,007	11/20/2003	Randolph Mellus Johnson	DURE-007CON2	9101

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,007	JOHNSON ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and terminal disclaimer, both filed 19/19/2006.

Claims 48-91 are pending. Claims 92-99 have been added.

Claims 48-99 are pending and included in the prosecution.

Terminal Disclaimer

1. The terminal disclaimer filed on 12/19/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US application 11/044,521 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The following new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 48-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,057,318 ('318) combined with US 5,890,927 ('927).

US '318 teaches implantable osmotic drug delivery devices that can be highly loaded of beneficial agents and able to deliver active beneficial agents at a controlled rate continuously over time and over a broad range of dosage delivery rates according to predetermined time release pattern (abstract; col.3, lines 20-26, 30-34, 39-42; col.19, lines 27-30; col. 20, lines 20, 34). Example of the drugs suitable for delivery by the implantable osmotic device is analgesic (col.13, lines 60-61).

US '318 does not specifically teach fentanyl and sufentanil as the analgesic drug, or doses and periods of delivery, i.e. the patterned delivery regimen, as instantly claimed.

However, US '318 recognized highly loading of beneficial agents including

analgesics and their delivery at a controlled rate continuously over time and over a broad range of dosage delivery rates according to predetermined time release pattern. This teaching would have motivated one having ordinary skill in the art to use the implantable osmotic device to deliver analgesics that need continuous delivery and manipulate the amount of analgesic and its period of delivery according to the specific patient need.

US '927 teaches method for continuous administration of analgesics from implantable device for prolonged period of time up to several months (abstract; col.6, lines 66-67). The two preferred analgesics are fentanyl and sufentanil because of their high potency (col.4, lines 38-43). The amount and delivery rate of the active agent do not impart patentability to the claims, absent evidence to the contrary. It is within the skilled artisan to manipulate the amount of the active agent to achieve a specific delivery profile according to specific patient need.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide implantable osmotic device to deliver analgesics at a controlled rate continuously over time and over a broad range of dosage delivery rates according to predetermined time release pattern as disclosed by US '318, and replace the analgesic with fentanyl or sufentanil as disclosed by US '927, motivated by the teaching of US '927 that fentanyl and sufentanil are preferred analgesic because of their high potency, with reasonable expectation of having implantable osmotic device highly loaded with fentanyl and sufentanil and able to deliver them at a controlled rate continuously over time and over a broad range of dosage delivery rates according to

predetermined time release pattern according to the patient condition with great success.

Response to Arguments

5. Applicant's arguments filed 12/19/2006 have been fully considered but they are not persuasive. Applicants traverse this rejection by arguing that:

- No motivation to combine US '318 and US '167 because US '318 is an implantable device and US '167 is not, and there would have been no expectation that fentanyl or its congener could have been used by implantable device as recited by the present claims.

In response to this argument, and by virtue of applicants' amendment to the claims to recite the limitation "implantable", a new ground of rejection is necessitated as set forth in section 4 of this office action, and the argument is rendered moot in view of the new ground of rejection.

- Applicants argue that US '318 does not provide specific guidance regarding the types of compounds covered under the broad disclosure of the reference. Although applicants admit that the reference teaches analgesics, yet argue that the general disclosure of analgesics would not cause one to expect fentanyl and its congers to be suitable for use with implantable device.

In response to this argument, US '318 teaches the suitability of analgesics to be delivered by implantable osmotic pumps and also teaches controlled delivery rate continuously over time and over a broad range of dosage delivery rates according to predetermined time release pattern, and one of ordinary skill in the art seeking for prolonged delivery of analgesics for persistent pain would deliver such analgesics from the implantable pump disclosed by US '318. It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

- Any motivation to select fentanyl or its congers must come from applicants' disclosure representing impermissible hindsight.

In response to this argument, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

- The claimed high concentration of fentanyl was not known in the field of pharmacology at the time of the invention which is up to 10,000 times or greater than the solubility of fentanyl in aqueous solution, such high concentration is not obvious.

In response to this argument, the reference does not specifically teach the amounts claimed by applicant, but suggests broad ranges of active agents over prolonged periods of time. The amount of a drug is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize according to the condition to be treated. Optimization of drug dose is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of the fentanyl or sufentanil in order to best achieve the desired results of prolonged pain relief. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of drug amount would have been obvious at the time of applicant's invention. The claimed amounts are known in the art to relieve pain and disclosed by WO 98/49402.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,412,139 teaches osmotic device for controlled and continuous delivery of beneficial drug over a prolonged period of time to produce systemic effect. The device can be implanted. This device can deliver analgesics. WO

97/94402 disclosed sustained release composition of sufentanil to relief pain for up to 48 hr. and composition deliver preferably from 100 pg/24 hr to 10 mg/24 hr which is equivalent to about 4 μg/hr to 400 μg/hr.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Primary Examiner
Art Unit 1615

IG

Isis Ghali.

ISIS GHALI
PRIMARY EXAMINER